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10/076,074	02/15/2002	Matthew C. Coffey	032775-091	8498

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EXAMINER	
LI, BAO Q	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 05/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/076,074	COFFEY ET AL.	
	Examiner	Art Unit	
	Bao Qun Li	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6,8-11,16,22,26-30 and 36-51* is/are pending in the application.

4a) Of the above claim(s) *31-35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6, 8-11, 16, 22, 26-30, 35-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 04/01/2004 & 09/27/2004
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

This is a response to the amendment filed on 02/23/06. Claims 1-5, 7, 12-15, 17-21, 23-25 have been canceled. Claims 6, 8, 22, 26, 27 have been amended. New claims 35-51 are added. Claims 31-35 were withdrawn from the consideration, Claims 6, 8-11, 16, 22, 26-51 are pending before the examiner. Claims 6, 8-11, 16, 22, 26-30 and 35-51 are considered.

Please note any ground of rejection(s) that has not been repeated is removed. Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

New Matter Objection

1. The claim 26, 6, 8-11, 16 and 27-30, 35-51 filed on 01/14/2005 are still objected to under 35 U.S.C. 132 on the same ground as stated in the previous office action because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention.

2. In response to this objection raised in the previous office action, Applicants have amended claim 26, 6, 8, 16 22, and submit that the disclosure at page 22, lines 8-15 of specification of current application describe the use of reovirus to treat a subject "at the onset of the course of chemotherapy such that all cells are killed or inhibited, including resistant cells." Applicants further argue that "Clearly a "course of chemotherapy" given at a subject where "all the cells" including drug sensitive cells as well as drug resistance cells identified a subject including neoplastic cells susceptible to a chemotherapeutic agent."

3. Applicants' argument has been respectfully considered; however it is not found persuasive to overcome the rejection. Though applicants can argue that the identification process can inherently occur during the treatment, a reasonable interpretation of the newly added step (a) in claim 26 reads on said step (a) occurs as an individual step separately ahead of treatment step cited in step (b) and (c), wherein the step (b) and step (c) can occur consequently or concurrently. Moreover, the course of using reovirus at the onset of the course of chemotherapy cannot be used as an identification process because it cannot give any identification whether the subject is susceptible for the chemotherapeutic agent since the co-administration of reovirus and

chemotherapeutic agent together kill the neoplastic cells in all no matter whether the neoplastic cells are susceptible or not susceptible to a chemotherapeutic agent.

4. The example taught in the specification also describes co- administration of reovirus with a chemotherapeutic agent Cisplatin. There is no additional step of identification if the subject is susceptible for the chemotherapeutic agent is processed prior to the administration of the reovirus to the animal implanted with the tumor.

5. Because the inserted new step (a) of claim 26 is directed to an active step rather than an inherent condition taught by the specification, absence of teaching such active step in the specification, the new matter objection is maintained. Moreover since applicants amend claims 6, 8-11, 16 and 22 to depend on claim 26, they are all affected by the objection of claim 26. Applicants are still required to cancel the new matter in order to overcome the objection.

6. To this context, the amendment filed on 02/23/2006 including the newly amended claims 27-28 as well as all their depended claims are also objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added materials in claims 27, 28 and 35-51 are not supported by the original disclosure because they all cite the step (a) that is objected by the examiner for the same notion as described above.

7. Applicants are also required to cancel the new matter in the reply to this Office Action.

New Matter Rejection

8. Claims 26-30, 6, 8-11, 16 and claims 27-30, 35-51 are still rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

9. In response to this objection raised in the previous office action, Applicants have amended claim 26, 6, 8, 16 22, and submit that the disclosure at page 22, lines 8-15 of specification of current application describe the use of reovirus to treat a subject "at the onset of the course of chemotherapy such that all cells are killed or inhibited, including resistant cells." Applicants further argue that "Clearly a "course of chemotherapy" given at a subject where "all

the cells" including drug sensitive cells as well as drug resistance cells identified a subject including neoplastic cells susceptible to a chemotherapeutic agent."

10. Applicants' argument has been respectfully considered; however it is not found persuasive to overcome the rejection. Though applicants can argue that the identification process can inherently occur during the treatment, a reasonable interpretation of the newly added step (a) in claim 26 reads on said step (a) occurs as an individual step separately ahead of treatment step cited in step (b) and (c), wherein the step (b) and step (c) can occur consequently or concurrently. Moreover, the course of using reovirus at the onset of the course of chemotherapy cannot be used as an identification process because it cannot give any identification whether the subject is susceptible for the chemotherapeutic agent since the co-administration of reovirus and chemotherapeutic agent together kill the neoplastic cells in all no matter whether the neoplastic cells are susceptible or not susceptible to a chemotherapeutic agent.

11. The example taught in the specification also describes co- administration of reovirus with a chemotherapeutic agent Cisplatin. There is no additional step of identification if the subject is susceptible for the chemotherapeutic agent is processed prior to the administration of the reovirus to the animal implanted with the tumor.

12. Because the inserted new step (a) of claim 26 is directed to an active step rather than an inherent condition taught by the specification, absence of teaching such active step in the specification, the new matter rejection is maintained. Moreover since applicants amend claims 6, 8-11, 16 and 22 to depend on claim 26, they are all affected by the rejection of claim 26. Applicants are still required to cancel the new matter in order to overcome the rejection.

13. To this context, the amendment filed on 02/23/2006 including the newly amended claims 27-28 as well as all their depended claims are also objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added materials in claims 27, 28 and 35-51 are not supported by the original disclosure because they all cite the step (a) that is rejected by the examiner for the same notion as described above.

14. Applicants are required to cancel the new matter in the reply to this Office Action.

New Ground Rejections:

15. The following rejections are based on the interpretations by applicants in the response filed on Feb. 23, 2006 that the identification step of (a) in claims 26, 27 and 28 occur concurrently with the steps (b) and (c) of administering the reovirus and chemotherapeutic agent. Moreover, the limitation of preventing a ras-activated neoplasm from developing drug resistance to a chemotherapeutic agent is not considered as an active step in all claims because it merely cites the purpose of the method and it does not add any manipulation step of the claimed method. To this context, the following rejections are still applied.

Double Patenting

16. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

17. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

18. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

19. Claims 6, 8-11, 16 and 26-30, 36-51 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 28 of U.S. Patent No. 6,565,831B1) in view of disclosure of Smith (Exp. Opin. Invest. Drugs, 2000, Vol. 9, No. 2, pages 311-327).

20. An obviousness-type double-patenting rejection is appropriate where the conflict claims are not identical but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim(s) is either anticipated by or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 14U F.3d 1428, 46 USPQZd 1226 (Fed. Cir. 1998);

In re Goodman, 11 F.3d 1046, 29 USPQZd 2010 (Fed. either anticipated by, 1993); In re Longi, F.2d 887, 225 US/Q 645 (Fed. Cir. 1985).

21. In the instant case, in the response filed on Feb. 23, 2006, applicants interpret that the identification step of (a) in claims 26, 27 and 28 occur concurrently with the steps (b) and (c) of administering the reovirus and chemotherapeutic agent. To this context, there is not more step different from the disclosure by cited prior art, the following rejection is still applied.

22. Moreover, the limitation of preventing a ras-activated neoplasm from developing drug resistance to a chemotherapeutic agent is not considered as an active step in all claims because it merely cites the purpose of the method and it does not add any manipulation step of the claimed method.

23. Hence claimed invention would have been obvious over, the reference claim(s) in view of the disclosure by Smith et al.

24. Claims 6, 8-11, 16 and 26-30, 36-51 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3-8,13-20, 24-33 and 34 of U.S. Patent No. 6,136,307A) in view of the disclosure of Smith (Exp. Opin. Invest. Drugs, 2000, Vol. 9, No. 2, pages 311-327).

25. An obviousness-type double-patenting rejection is appropriate where the conflict claims are not identical but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim(s) is either anticipated by or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 14U F.3d 1428, 46 USPQZd 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQZd 2010 (Fed. either anticipated by, 1993); In re Longi, F.2d 887, 225 US/Q 645 (Fed. Cir. 1985).

26. In the instant case, in the response filed on Feb. 23, 2006, applicants interpret that the identification step of (a) in claims 26, 27 and 28 occur concurrently with the steps (b) and (c) of administering the reovirus and chemotherapeutic agent. To this context, there is not more step different from the disclosure by cited prior art, the following rejection is still applied.

27. Moreover, the limitation of preventing a ras-activated neoplasm from developing drug resistance to a chemotherapeutic agent is not considered as an active step in all claims because it merely cites the purpose of the method and it does not add any manipulation step of the claimed method.

28. Hence claimed invention would have been obvious over, the reference claim(s) in view of the disclosure by Smith et al.

Claim Rejections - 35 USC § 103

29. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

30. Claims 6, 8-11, 16 and 26-30, 36-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. (US Patent No. 6,136,307A) in view of Smith (Exp. Opin. Invest. Drugs, 2000, Vol. 9, No. 2, pages 311-327).

31. In the instant case, in the response filed on Feb. 23, 2006, applicants interpret that the identification step of (a) in claims 26, 27 and 28 occur concurrently with the steps (b) and (c) of administering the reovirus and chemotherapeutic agent. To this context, the following rejection is still applied. Moreover, the limitation of preventing a ras-activated neoplasm from developing drug resistance to a chemotherapeutic agent is not considered as an active step in all claims because it merely cites the purpose of the method and it does not add any manipulation step of the claimed method.

32. Therefore, it would have been obvious for a person with ordinary skill in the art to be motivated using less dosage of therapeutic agent in combination of the enclitic reovirus to treat ras-mediated neoplasm with much better anti-tumor effect since reovirus is particularly suitable for oncolyzing the ras-mediated neoplastic cell and combination of reovirus with a chemotherapeutic agent produces a synergistic effect. The claimed invention is prima facie obvious absence unexpected results.

33. Claims 6, 8-11, 16 and 26-30, 36-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. (WO 00/50051A2) in view of Smith et al. (Exp. Opin. Invest. Drugs, 2000, Vol. 9, No. 2, pages 311-327).

34. In the instant case, in the response filed on Feb. 23, 2006, applicants interpret that the identification step of (a) in claims 26, 27 and 28 occur concurrently with the steps (b) and (c) of

administering the reovirus and chemotherapeutic agent. To this context, there is not more step different from the disclosure by cited prior art, the following rejection is still applied.

35. Moreover, the limitation of preventing a ras-activated neoplasm from developing drug resistance to a chemotherapeutic agent is not considered as a active step in all claims because it merely cites the purpose of the method and it does not add any manipulation step of the claimed method.

36. Therefore, it would have been obvious for a person with ordinary skill in the art to be motivated using less dosage of therapeutic agent in combination of the oncolytic reovirus to treat ras-mediated neoplasm with much better anti-tumor effect. The claimed invention is prima facie obvious absence unexpected results.

37. Claims 6, 8-11, 16 and 26-30, 36-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al. (Exp. Opin. Invest. Drugs, 2000, Vol. 9, No. 2, pages 311-327).

38. In the instant case, in the response filed on Feb. 23, 2006, applicants interpret that the identification step of (a) in claims 26, 27 and 28 occur concurrently with the steps (b) and (c) of administering the reovirus and chemotherapeutic agent. To this context, there is not more step different from the disclosure by cited prior art, the following rejection is still applied.

39. Moreover, the limitation of preventing a ras-activated neoplasm from developing drug resistance to a chemotherapeutic agent is not considered as a active step in all claims because it merely cites the purpose of the method and it does not add any manipulation step of the claimed method.

40. Therefore, it would have been obvious for a person with ordinary skill in the art to be motivated using less dosage of therapeutic agent in combination of the oncolytic reovirus to treat ras-mediated neoplasm with much better anti-tumor effect since reovirus is particularly suitable for oncolyzing the ras-mediated neoplastic cell and combination of reovirus with a chemotherapeutic agent produces a synergistic effect. The claimed invention is prima facie obvious absence unexpected results.

41. Claims 6, 8-11, 16 and 26-30, 36-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mercer University (Mercer University Home page 1996, pp. 1-2) in view of Smith et al. (Exp. Opin. Invest. Drugs, 2000, Vol. 9, No. 2, pages 311-327).

42. Mercer University published on its home page that disclose that Dr. Steele give mice a combination of reovirus type 3 and a chemotherapeutic compound BCUN , resulting in 100% implanted tumor reduction (see entire document). Regarding to the limitations of the recitation of "sensitizing" or "preventing" a neoplastic cell to a chemotherapeutic agent, Office considered these recitation as preamble languages, which do not change the manipulating steps of the method comprising administration of reovirus and a chemotherapeutic agent into a population of neoplastic cells that result in a reduction of the neoplastic cells growth in vitro or in vivo. Mercer University does not teach that the reovirus is suitable for using with reovirus, and combination of reovirus and a chemotherapeutic agent can reduce the dosage of the chemotherapeutic agent.

43. Smith et al. teach that oncolytic reovirus treatment of cancer is particularly susceptible and effective for the ras-mutated cancer, and combined oncolytic reovirus and a chemotherapeutic agent treatment is more superior to any of the agent used alone. For reovirus, such synergistic therapeutic effect can produce a rate of 80% complete tumor remission (See pages 319, 1st paragraph of section 7 and 1st paragraph of section 9 on page 321).

44. Because in the response filed on Feb. 23, 2006, applicants interpret that the identification step of (a) in claims 26, 27 and 28 occur concurrently with the steps (b) and (c) of administering the reovirus and chemotherapeutic agent. To this context, there is not more step different from the disclosure by cited prior art, the following rejection is still applied.

45. Moreover, the limitation of preventing a ras-activated neoplasm from developing drug resistance to a chemotherapeutic agent is not considered as a active step in all claims because it merely cites the purpose of the method and it does not add any manipulation step of the claimed method.

46. Therefore, it would have been obvious for a person with ordinary skill in the art to be motivated using less dosage of therapeutic agent in combination of the oncolytic reovirus to treat ras-mediated neoplasm with much better anti-tumor effect since reovirus is particularly suitable for oncolyzing the ras-mediated neoplastic cell and combination of reovirus with a chemotherapeutic agent produces a synergistic effect. The claimed invention is prima facie obvious absence unexpected results.

Claim Rejections - 35 USC § 102

47. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless

–(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

48. Claims 6, 8, 9-11, 16, 22, 26-28 and 36-51 are rejected under 35 U.S.C. 102(a) as being anticipated by Lee et al. (A) (US Patent No. 6,136,307A).

49. Lee et al. teach a method of treating ras-mediated proliferation disorder in a mammal comprising administration of a reovirus or a pharmaceutical composition comprising a reovirus and a chemotherapeutic agent into a mammal suffering a ras-mediated neoplasm (See lines 11-14 on col. 11 and claims 1, 3-8,13-20, 24-33 and 34), wherein the chemotherapeutic agent is selected from the same group of chemotherapeutic agents including cisplatin (See lines 1-15 on column 12). Hence, the disclosure by Lee et al. (A) anticipates the claimed invention.

50. Because in the response filed on Feb. 23, 2006, applicants interpret that the identification step of (a) in claims 26, 27 and 28 occur concurrently with the steps (b) and (c) of administering the reovirus and chemotherapeutic agent. To this context, there is not more step different from the disclosure by Lee et al. (A) in US patent "307A), the following rejection is still applied.

51. Regarding to the limitations of the recitation of "sensitizing" or "preventing" or the purpose or result of the methods cited claims 26, 27 28 and claims 30, 43, Office considered these recitations are not an active step in the claimed invention, which do not change the manipulating steps of the claimed method. Because active steps of claimed methods are same, they will end up with the same biological effects, they are also anticipated by the disclosure of the claims 1, 3-8,13-20, 24-33 and 34 of U.S. Patent No. 6,136,307A.

52. Claims 6, 8, 9-11, 16, 22, 26-28 and 36-51 are rejected under 35 U.S.C. 102(a) as being anticipated by Lee et al. (B) (WO 00/50051A2).

53. Lee et al. (B) teach a method of treating ras-mediated proliferation disorder in a mammal comprising administration of a reovirus or a pharmaceutical composition comprising a reovirus and a chemotherapeutic agent into a mammal suffering a ras-mediated neoplasm (See lines 1-4 on 7 and claims 1, 3-7, 11-20, 27-31, 33-38 and 41), wherein the chemotherapeutic agent is

selected from the same group of chemotherapeutic agents including cisplatin (See lines 9-18 on page 22). Hence, the disclosure by Lee et al. (B) anticipates the claimed invention.

54. Because in the response filed on Feb. 23, 2006, applicants interpret that the identification step of (a) in claims 26, 27 and 28 occur concurrently with the steps (b) and (c) of administering the reovirus and chemotherapeutic agent. To this context, there is not more step different from the disclosure by Lee et al. (A) in US patent "307A), the following rejection is still applied.

55. Regarding to the limitations of the recitation of "sensitizing" or "preventing" or the purpose or result of the methods cited claims 26, 27 28 and claims 30, 43, Office considered these recitations are not an active step in the claimed invention, which do not change the manipulating steps of the claimed method. Because active steps of claimed methods are same, they will end up with the same biological effects, they are also anticipated by the disclosure by Lee et al. (B).

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 6:30 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BAOQUN LI, MD
PATENT EXAMINER

Bao Qun Li 05/09/06